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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,658	11/29/2001	James M. Coull	BP-0002-1 US	5256

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LIFE TECHNOLOGIES CORPORATION
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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
10/05/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LifetechDocket@system.foundationip.com

Office Action Summary	Application No.	Applicant(s)	
	09/996,658	COULL ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2010 & 06 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

5a) Of the above claim(s) *69-86* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,4,5,7,8,11,15-18,21,22,24-26,29-31,35,38,39,41-43,46-48 and 60-68* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☒ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,4,5,7,8,11,15-18,21,22,24-26,29-31,35,38,39,41-43,46-48 and 60-86.

DETAILED ACTION

Election/Restrictions

1. Newly-added claims 69-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09 March 2004.

Specification

2. The specification contains numerous bibliographic citations, and states at page 8, lines 18-19, and at page 11, lines 12-13, that "all of which are herein incorporated by reference." The specification also states at page 13, line 20, and page 14, line 26, that the documents are "herein incorporated by reference." As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that a one

> sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application). (Emphasis added.)

Attention is also directed to MPEP 201.06(c), which, in pertinent part, is reproduced below:

> The inclusion of this incorporation by reference statement will permit an applicant to amend the continuation or divisional application to include subject matter from the prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the incorporation by reference. For applications filed prior to September 21, 2004, the incorporation by reference statement may appear in the transmittal letter or in the specification. Note that for applications filed prior to September 21, 2004, if applicants used a former version of the transmittal letter form provided by the USPTO, the incorporation by reference statement could only be relied upon to add inadvertently omitted material to the continuation or divisional application.
> For applications filed on or after September 21, 2004, a claim under 35 U.S.C. 120 and 37 CFR 1.78 for benefit of a prior-filed nonprovisional application or international application designating the U.S. that was present on the filing date of the continuation or divisional application is considered an incorporation by reference of the prior-filed application as to inadvertently omitted material, subject to the conditions and requirements of 37 CFR 1.57(a). (Emphasis added)

Accordingly, the cited documents are not considered to have been incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Response to argument

3. At page 16, bridging to page 17, of the response of 21 August 2010, applicant's representative reasserts that for reasons of record, the objection is traversed. It is also asserted that "Applicants do not rely on the incorporated references for descriptive support of particular limitations in the claims" and as such, the objection to the specification should be withdrawn as it is without "particular purpose."

4. The above argument has been considered and has not been found persuasive. To the degree that applicant renews prior traversals, such arguments have been considered and have not been found persuasive. At pages 15-16 of the response received 20 September 2005, applicant's representative asserts that the objection to the specification should be withdrawn, citing that the citing of Advanced Display Systems Inc. is "misplaced." This traversal has not been found persuasive. As set forth in *Ex parte Raible*, 8 USPQ2d 1709, (BPAI, 1998)

> The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree.
> ***
> We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon .to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. *In re de Seversky*, 474 F.2d 671,177 USPQ 144, (CCPA 1973).
> ***
> For the sake of completeness, we take notice of the decision in *In re Voss* , 557 F.2d 812, 194 USPQ 267 (CCPA 1977). We recognize that *Voss* , like the present case, involved an attempt to rely upon the incorporation by reference of a U.S. patent for descriptive support of a particular limitation in the claims. However, the decision in *Voss* is not dispositive of the issue before us, and is distinguishable on its facts for the following reasons:
> (1) In *Voss* , the incorporating statement particularly referred to the aspect of the patent which was being relied upon, i.e., "for a general discussion of glass-ceramic materials and their production". Here, as previously indicated, there is no reference in the incorporating statement to any specific portion or aspect of the Bentley disclosure. Actually, the incorporating statement involved here more broadly refers to several patents with no specific indication of the relevance of each to the claimed invention.

The case at hand is analogous to that of *Raible* in that applicant seeks to incorporate by reference into the disclosure a number of documents when the specification "broadly refers to several

patents [and non-patent documents] with no specific indication of the relevance of each to the claimed invention." Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph. While an applicant may utilize bibliographic citations in an application's specification so to establish the level of skill and/or state of the art at the time of filing, such documents, as is here, have not been properly incorporated so as to be useful in satisfying either the written description or best mode requirements of 35 USC 112, first paragraph. Additionally, to the extent that the documents contains essential subject matter required for the enablement of the claims, and said document is not an issued US patent, said documents cannot be relied upon for satisfaction of the enablement requirement of 35 USC 112, first paragraph.

5. In regard to applicant's assertions that they are not currently relying upon the disclosures for satisfaction of any "particular limitation," it is noted that applicant, at page 19 of the response of 21 August 2010, directs attention to paragraphs that contain substantial listing of incorporated documents as satisfying the written description requirement for "microbes," "binding partner," "peptide nucleic acids," and "detectable molecular probe." So contrary to assertions made by applicant at page 17 of the response, applicant, at page 19 of the same response is explicitly directing attention to these very documents as providing the needed written description.

6. For the above reasons, and in the absence of convincing evidence to the contrary, the objection to the specification is maintained.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 4, 5, 7, 8, 11, 15-18, 21, 22, 24-26, 29-31, 35, 38, 39, 41-43, 46-48, and 60-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. Claims 1, 18, 35, and 60 are the only independent claims pending and under consideration. Claim 60 is deemed representative and, for convenience, is reproduced below.

60. (New) A method for determining the presence of a microbial organism of interest in a sample from another organism or organisms, said method comprising:

(1) treating the sample, or a portion thereof, with at least one detectable molecular probe wherein the molecular probe or probes are peptide nucleic acid and are selected such that either:

(i) a target sequence of both the microbial organism of interest and the other organism or organisms reacts with the molecular probe in a way that produces detectable microbial organisms of interest and a detectable other organism or organisms; or

(ii) a target sequence of only the microbial organism of interest reacts with the molecular probe in a way that produces only detectable organisms of interest;

(2) contacting the sample, or a portion thereof, with a solid carrier to which has been immobilized an antibody such that:

if (i) applies then the antibody is chosen to be reactive only with the detectable microbial organism of interest but not reactive with the detectable other organism or organisms; but

if (ii) applies then the antibody is chosen to be generally reactive with the detectable microbial organism of interest but also may be reactive with the other organism or organisms; and

(3) determining the presence of detectable microbial organisms immobilized to the solid carrier,

wherein the microbial organism of interest is consisting of a cell, a bacterium, a virus, a yeast, a fungus, another unicellular organism and a multicellular organism.

10. Attention is directed to MPEP 904.01.

> The breadth of the claims in the application should always be carefully noted; that is, the examiner should be fully aware of what the claims do not call for, as well as what they do require. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). See MPEP § 2111 - § 2116.01 for case law pertinent to claim analysis.

11. It is noted with particularity that narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. *In re Philips Industries v. State Stove & Mfg. Co, Inc.*, 186 USPQ 458 (CA6 1975). While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into the claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992).

12. As see above, the method as set forth in amended claim 1 encompasses at least two alternative embodiments:

a. "a target sequence of both the microbial organism of interest and the other organism or organisms reacts with the molecular probe in a way that produces detectable microbial organisms of interest and a detectable other organism or organisms;" and

b. "a target sequence of only the microbial organism of interest reacts with the molecular probe in a way that produces only detectable organisms of interest."

13. Page 7 of the disclosure is found to provide the following definitions:

> As used herein, the term "probe" or "molecular probe" means a nucleic acid or non-nucleic acid polymer (e.g. a DNA, RNA, PNA, nucleic acid analogs, nucleic acid mimics, chimera or linked polymer) having a probing nucleobase sequence that is designed to sequence specifically hybridize to a target sequence of a target molecule of an organism of interest.
>
> As used herein, a "target sequence" is the nucleobase sequence of a nucleic acid that is found in an organism of interest and to which a molecular probe is designed to hybridize sequence specifically thereto.

14. As set forth in *In re Alonso* 88 USPQ2d 1849 (Fed. Cir. 2008), at 1851:

> The written description requirement of 35 U.S.C. § 112, ¶ 1, is straightforward: "The specification shall contain a written description of the invention …." To satisfy this requirement, the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997); *see also LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 [76 USPQ2d 1724] (Fed. Cir. 2005); *Eiselstein v. Frank*, 52 F.3d 1035, 1039 [34 USPQ2d 1467] (Fed. Cir. 1995).

Alonso at 1852:

> A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when

> coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo*, 323 F.3d at 964.

15. In applying the test as set forth in *Alonso*, it is noted that applicant is claiming a generic method of "determining the presence of a microbial organism of interest." The microbe of interest is without limit in independent claims 1, 18, and 35, yet in independent claim 60, it fairly encompasses not only any and all manner of cells, but also viruses (see step (3)). At page 19 of the disclosure, applicant states:

> The assay user or designer will select the organism of interest. As used herein, the organism of interest is a microorganism, tissue or microscopic sized cell. The organism of interest may be a cell, bacteria, virus, yeast, fungi, other unicellular organism or a multicellular organism. Thus, there are no limitations in the organism of interest except that it be microscopic in size.
>
> The organism of interest is generally selected to be an organism characterized by domain, kingdom, group, class, genus, species, taxon, subclass, subspecies, serotype, strain or by any other recognized means of characterization of the organism of interest. Optionally, but not necessarily, the organism of interest will be chosen such that it is to be distinguished from a closely related organism or organisms wherein an antibody or probe based assay, alone, is not adequate to properly characterize the organism of interest from the organism or organisms to be distinguished.

It is noted that applicant has not restricted or in any way limited the genera of organisms or microbial organism. Accordingly, the claimed method has been construed to encompass the determination of the presence of any and all manner of "microbial organisms" of interest, be it prokaryotic (e.g., bacteria and archaea) or eukaryotic (e.g., protists, microscopic arthropods, including dust mites and spider mites; microscopic crustaceans, such as copepods and cladocera, nematodes, rotifers, fungi, and plants such as certain algae.).

16. In looking at just one component of the genus, bacteria, it is noted that even at this date, the number of bacteria that exists, much less the nucleotide sequence of same is unknown. As stated in "How Many Species of Bacteria Are There" (2011):

> Estimating the exact number of species of bacteria is impossible with today's technology. To really move close to having an objective number, you'd have to have a machine that could process soil, water, and rock in large amounts, isolate the bacteria from their habitat, then sequence the genomes of as many bacteria as possible within the sample.
>
> Today, given that sequencing a bacterial genome costs half a million dollars and takes a few months, this is infeasible. Even if costs fall by a factor of a trillion, there are so many microbes in soil that categorizing them in this way would be prohibitively expensive.
>
> ***
>
> One survey found 20,000 species of bacteria in a liter of seawater.
>
> ***
>
> Currently, estimates of the total number of species of bacteria range from about 10 million to a billion, but these estimates are tentative…

17. The above showing clearly establishes that 1) the genus is vast and encompasses millions, if not billions, of just bacteria, the nucleotide sequence of same not being known, and is unattainable, even at this date.

18. As noted above, applicant considers the claimed method and the probes required for its operation, to encompass any and all manner of microbial organism, which is a tremendously vast and highly divergent genus.

19. The claimed method has also been construed as encompassing the simultaneous determination of the "presence or number" of multiple microbial organisms of interest. In support of this position, attention is directed to page 29 of the specification, which states in part:

> It should be noted, that the number of different organisms of interest that can be determined is limited only by the number of different independently detectable molecular probes that can be prepared and that five organisms per sample is not intended to be a

> limit on the method. Furthermore, it is evident that 100 different types of coded beaded supports is not intended to be a limit on the method.

20. Applicant, at page 36 of the disclosure states:

> Two types of coded beads were received from LUMINEX, one coated with Salmonella-specific antibody (OEM Concepts, Toms River, NJ; the "Salmonella beads") and one with Listeria-specific antibody (OEM Concepts, Toms River, NJ; the "Listeria beads").

21. A review of the disclosure finds that applicant has filed a Sequence Listing, and that this Sequence Listing consists of but a single oligonucleotide, which is some 15 nucleotides in length, and which applicant has identified as being an "Artificial PNA Probe."

22. The disclosure clearly indicates that the one and only example did not function as intended, and that applicant presents forward-looking statements as to their future plans to unravel "why the selected specificity was not achieved." Such explicit statements do not reasonably suggest that applicant had possession of the generic reagents needed to practice the full scope of the claimed invention. Indeed, even under conditions selected by applicant, the desired results were not obtained when but two microorganisms were selected.

23. Clearly, the example provided does not describe how one is to accurately and reproducibly determine the number of microbes present, much less in excess of 100 different microbial organisms of interest, and lesser still for the full breadth of scope for all possible "microbial organisms," regardless of their being prokaryotic or eukaryotic.

24. At page 17 of the disclosure applicant recognizes that one will need to "harmonize" conditions for both antibody binding and PNA binding/hybridization. Rather than describe suitable conditions, applicant is seemingly looking to the future, and what the public will be able to resolve. As stated therein:

> When employing the methods of this invention or in the production of the compositions of this invention, it may be important to harmonize the hybridization conditions with the antibody binding conditions because the staining of the organisms is performed simultaneously with, or subsequent to, an antibody binding event. Because optimization of the same variables (pH, salt concentration etc.) is involved, aided by no more than routine experimentation, those of skill in the art will easily be able to harmonize the antibody binding conditions and suitable hybridization conditions for performing an assay. It should however be noted that the use of non-nucleic acid, and preferably PNA probes, is preferred when harmonization of the hybridization and antibody binding conditions is required because PNA probe bind more tightly under conditions of physiological salt, conditions under which antibodies are more likely to operate most efficiently. (Emphasis added)

For purposes of examination, the claimed method has been construed as encompassing harmonization of conditions between PNA probes and antibodies, as both are required in the present claims. Further, the claimed method has been construed as encompassing both simultaneous and sequential binding of PNA probe and antibody. Again, the specification does not set forth an adequate written description of the conditions to be employed.

25. The specification extols the virtues of using blocking probes, however, the claimed method has been construed as not requiring any blocking probe, and yet binding of probe to non-target nucleic acid sequence can reasonably be expected to occur and result in false signals. The specification has not been found to describe how signals resulting from probe binding to target vs. non-target nucleic acids are to be correctly and reproducibly detected when the same signal from binding of probe to non-target nucleic acids is occurring.

26. While agreement is reached with applicant at page 20 of the response of 21 August 2010 that an applicant is not required to teach each and every possible embodiment encompassed by the claims, applicant is still required to provide a sufficient teaching in such full, clear and exact terms so as to reasonably suggest that applicant had possession of the entire genus of that being claimed- at the time of filing. While applicant has defined the terms of the various probes in

terms of how they are to function, hybridize to a common sequence found in different organisms, or are specific for a particular (specie, subspecies or variant) of bacteria, fungi, viruses, multicellular organisms, etc., such a description does not constitute an adequate written description of the probes that are required for one of skill in the art to practice the full scope of the claimed invention. In support of this position, attention is directed to the decision of *University of California v. Eli Lilly and Co.* (CA FC, July 1997) 43 USPQ2d 1398 wherein is stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

27. At page 19 of the response of 21 August 2010, applicant directs attention to paragraphs [0006], [0018], and [0027] as providing a description of the PNA probes required of the claimed

method; and to paragraphs [0023], [0026], and [00137] of the disclosure as providing a description of the "detectable molecular probe." The preceding argument has been considered and has not been found persuasive as the cited passages all refer to how the various probes are to function within the context of the claimed invention. As noted above: "[N]aming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

28. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

29. In view of the limited showing, and the fact that applicant admits that "the selected specificity was not achieved," the disclosure has not been found to satisfy either prong of the written description test (disclose either "(1) a representative number of species in that genus; or (2) its 'relevant identifying characteristics,' such as 'complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics'").

30. For the above reasons, an in the absence of convincing evidence to the contrary, claims 1, 4, 5, 7, 8, 11, 15-18, 21, 22, 24-26, 29-31, 35, 38, 39, 41-43, 46-48, and 60-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Conclusion

31. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

33. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571)272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634